

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

December 4, 2000

0260 '00 DEC -8 A9:54

Gaithersburg Holiday Inn

Two Montgomery Village Avenue, Gaithersburg, MD

10:00 a.m.	Call to Order	Cynthia Tracy, M.D. Acting Chairperson
	Conflict of Interest Statement	Megan Moynahan Executive Secretary
10:15 – 10:45 a.m.*	Open Public Hearing*	
10:45 – 10:55 a.m.	FDA Introductory Remarks Lynette Gabriel, lead reviewer Food and Drug Administration	
10:55 – 12:00 noon	Sponsor Presentation Cass Pinkerton, M.D., Cardiologist Nasser, Smith, & Pinkerton Cardiology Neal E. Fearnot, Ph.D., President MED Institute, Inc.	
12:00 – 12:15 pm	FDA's Questions for the Panel Lynette Gabriel, lead reviewer Food and Drug Administration	
12:15 p.m.	Lunch	
1:15 p.m.	Open Committee Discussion	Cynthia Tracy, M.D. Acting Chairperson
3:00 – 3:15 p.m.	Break	
4:30 - 5:00 p.m.** (approx. time)	Open Public Hearing**	
6:00 p.m.	Adjourn	

OPEN PUBLIC HEARING*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Tracy will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.

Scheduled Speakers are given a ten-minute limit. Unscheduled speakers may have time designated by the Chair.

OPEN PUBLIC HEARING**

Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee.